Exhibit 2

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Symbicort® Turbuhaler® 80/4.5µg/dose
Symbicort® Turbuhaler® 160/4.5µg/dose

budesonide/formoterol

Inhalation powder

Composition

Each delivered dose (the dose that leaves the mouthpiece) contains as active constituents:
budesonide 80 micrograms/inhalation and formoterol fumarate dihydrate 4.5 micrograms/inhalation respectively budesonide 160 micrograms/inhalation and formoterol fumarate dihydrate 4.5 micrograms/inhalation.

Symbicort Turbuhaler 80/4.5 micrograms/inhalation delivers the same amount of budesonide and formoterol as the corresponding Turbuhaler monoproducts, i.e. budesonide 100 micrograms/inhalation (metered dose) and formoterol 6 micrograms/inhalation (metered dose) alternatively labelled as 4.5 micrograms/inhalation (delivered dose).

Symbicort Turbuhaler 160/4.5 micrograms/inhalation delivers the same amount of budesonide and formoterol as the corresponding Turbuhaler monoproducts, i.e. budesonide 200 micrograms/ inhalation (metered dose) and formoterol 6 micrograms/inhalation (metered dose) alternatively labelled as 4.5 micrograms/inhalation (delivered dose).

Indication

Symbicort Turbuhaler is indicated in the regular treatment of asthma where use of a combination (inhaled corticosteroid and long acting beta-agonist) is appropriate:

- patients not adequately controlled with inhaled corticosteroids and "as needed" inhaled short acting beta$_2$-agonists.

or

- patients already adequately controlled on both inhaled corticosteroids and long acting beta$_2$-agonists.

Note: Symbicort (80/4.5 micrograms/inhalation) is not appropriate in patients with severe asthma.

Dosage and method of administration

Symbicort Turbuhaler is not intended for the initial management of asthma. The dosage of the components of Symbicort Turbuhaler is individual and should be adjusted to the severity of the disease. This should be considered when treatment with combination products is initiated. If an individual patient should require dosages outside the recommended regimen, appropriate doses of beta-agonist and/or corticosteroids should be prescribed.

Patients should be regularly reassessed by a doctor, so that the dosage of Symbicort Turbuhaler remains optimal. The dose should be titrated to the lowest dose at which effective control of symptoms is maintained. When control of symptoms is maintained with the lowest recommended dosage, then the next step could include a test of inhaled corticosteroid alone.

Recommended doses:
Adults and adolescents (12 years and older):
Symbicort Turbuhaler 80/4.5 micrograms/dose 1-2 inhalations twice daily.
Symbicort Turbuhaler 160/4.5 micrograms/dose 1-2 inhalations twice daily.

In usual practice when control of symptoms is achieved with the twice daily regimen, titration to the lowest effective dose could include Symbicort Turbuhaler given once daily.

Children under 12 years: Efficacy and safety have not been fully studied in children. Symbicort is not recommended for children under 12 years of age.

Special patient groups: There is no need to adjust the dose in elderly patients. There are no data available for use of Symbicort Turbuhaler in patients with hepatic or renal impairment. As budesonide and formoterol are primarily eliminated via hepatic

Concomitant treatment with ketoconazole or other potent CYP3A4 inhibitors should be avoided. If this is not possible the time interval between administration of the interacting drugs should be as long as possible.

Symbicort Turbuhaler should be administered with caution in patients with thyrotoxicosis, phaeochromocytoma, diabetes mellitus, untreated hypokalaemia, hypertrophic obstructive cardiomyopathy, idiopathic subvalvular aortic stenosis, severe hypertension, aneurysm or other severe cardiovascular disorders, such as ischaemic heart disease, tachyarrhythmias or severe heart failure.

Caution should be observed when treating patients with prolongation of the QTc-interval. Formoterol itself may induce prolongation of the QTc-interval.

Potentially serious hypokalaemia may result from high doses of beta$_2$-agonists. Concomitant treatment with drugs which can induce hypokalaemia may add to a possible hypokalaemic effect from high doses of a beta$_2$-agonist. Particular caution is recommended in acute severe asthma as the associated risk may be augmented by hypoxia. The hypokalaemic effect may be potentiated by concomitant treatment with xanthine derivatives, steroids and diuretics. It is recommended that serum potassium levels are monitored during treatment of acute severe asthma.

As for all beta$_2$-agonists, additional blood glucose control should be considered in diabetic patients.

Symbicort Turbuhaler contains lactose (<1 mg/inhalation). This amount does not normally cause problems in lactose intolerant people.

Interactions

Ketoconazole 200 mg once daily increased plasma levels of concomitantly administered oral budesonide (single dose of 9 mg) on average six-fold. When ketoconazole was administered 12 hours after budesonide the concentration was on average increased three-fold. Information about this interaction is lacking for inhaled budesonide, but marked increases in plasma levels could be expected. Since data to give dosage recommendations are lacking, the combination should be avoided. If this is not possible, the time interval between administration of ketoconazole and budesonide should be as long as possible. A reduction in the dose of budesonide should also be considered. Other potent inhibitors of CYP3A4 are also likely to markedly increase plasma levels of budesonide.

Beta-adrenergic blockers can weaken or inhibit the effect of formoterol. Symbicort Turbuhaler should therefore not be given together with beta-adrenergic blockers (including eye drops) unless there are compelling reasons.

Concomitant treatment with quinidine, disopyramide, procainamide, phenothiazines, antihistamines (terfenadine), monoamine oxidase inhibitors and tricyclic antidepressives can prolong the QTc-interval and increase the risk of ventricular arrhythmias.

In addition L-Dopa, L-thyroxine, oxytocin and alcohol can impair cardiac tolerance towards β$_2$-sympathomimetics.

Concomitant treatment with monoamine oxidase inhibitors including agents with similar properties such as furazolidone and procarbazine may precipitate hypertensive reactions.

There is an elevated risk of arrhythmias in patients receiving concomitant anaesthesia with halogenated hydrocarbons.

Concomitant use of other beta-adrenergic drugs can have a potentially additive effect.

Hypokalaemia may increase the disposition towards arrhythmias in patients who are treated with digitalis glycosides.

Budesonide has not been observed to interact with any other drugs

metabolism, an increased exposure can be expected in patients with severe liver cirrhosis.

Instructions for correct use of Turbuhaler:
Turbuhaler is inspiratory flow-driven, which means that when the patient inhales through the mouthpiece, the substance will follow the inspired air into the airways.

Note: It is important to instruct the patient
- To carefully read the instructions for use in the patient information leaflet which is packed together with each inhaler
- To breathe in forcefully and deeply through the mouthpiece to ensure that an optimal dose is delivered to the lungs.
- Never to breathe out through the mouthpiece.
- To rinse the mouth out with water after inhaling the prescribed dose to minimise the risk of oropharyngeal thrush.

The patient may not taste or feel any medication when using Turbuhaler due to the small amount of drug dispensed.

Contra-indications
Hypersensitivity to budesonide, formoterol or inhaled lactose.

Special warnings and precautions for use
It is recommended that the dose is tapered when the treatment is discontinued.

D If patients find the treatment ineffective, or exceed the current dose of the fixed combination, medical attention must be sought.

E Increasing use of rescue bronchodilators indicates a worsening of the underlying condition and warrants a reassessment of the asthma therapy. Sudden and progressive deterioration in control of asthma is potentially life threatening and the patient should undergo urgent medical assessment. In this situation consideration should be given to the need for increased therapy with corticosteroids or addition of systemic anti-inflammatory therapy, such as a course of oral corticosteroids, or antibiotic treatment if an infection is present.

There are no data available on the use of Symbicort Turbuhaler in the treatment of an acute asthma attack. Patients should be advised to have their rescue medication available at all times.
Therapy should not be initiated during an exacerbation.

As with other inhalation therapy, paradoxical bronchospasm may occur, with an immediate increase in wheezing after dosing. If a severe reaction occurs, treatment should be reassessed and alternative therapy instituted if necessary.

Systemic effects may occur with any inhaled corticosteroid, particularly at high doses prescribed for long periods. These effects are much less likely to occur with inhalation treatment than with oral corticosteroids. Possible systemic effects include adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract and glaucoma. It is important, therefore, that the dose of inhaled corticosteroid is adjusted to the lowest dose at which effective control is maintained.

Physicians should closely follow the growth of children and adolescents taking long term corticosteroids by any route, and weigh the benefits of the corticosteroid therapy against the possible risk of growth suppression.

If there is any reason to suppose that adrenal function is impaired from previous systemic steroid therapy, care should be taken when transferring patients to Symbicort Turbuhaler therapy.

The benefits of inhaled budesonide therapy would normally minimise the need for oral steroids, but patients transferring from oral steroids may remain at risk of impaired adrenal reserve for a considerable time. Patients who have required high dose emergency corticosteroid therapy in the past may also be at risk. This possibility of residual adrenal impairment should always be borne in mind in emergency and elective situations likely to produce stress, and appropriate corticosteroid treatment must be considered. The extent of the adrenal impairment may require specialist advice before elective procedures.

To minimise the risk of oropharyngeal candida infection the patient should be instructed to rinse the mouth with water after each dosing occasion.

used in the treatment of asthma.

Pregnancy and lactation
For Symbicort Turbuhaler or the concomitant treatment with formoterol and budesonide, no clinical data on exposed pregnancies are available. Animal studies with respect to reproductive toxicity of the combination have not been performed.

There are no adequate data from use of formoterol in pregnant women. In animal studies formoterol has caused adverse effects in reproduction studies at very high systemic exposure levels.

Data on approximately 2000 exposed pregnancies indicate no increased teratogenic risk associated with the use of inhaled budesonide. In animal studies glucocorticosteroids have been shown to induce malformations. This is not likely to be relevant for humans given recommended doses.

Animal studies have also identified an involvement of excess prenatal glucocorticoids in increased risks for intrauterine growth retardation, adult cardiovascular disease and permanent changes in glucocorticoid receptor density, neurotransmitter turnover and behaviour at exposures below the teratogenic dose range.

During pregnancy, Symbicort Turbuhaler should only be used when the benefits outweigh the potential risks. The lowest effective dose of budesonide needed to maintain adequate asthma control should be used.

It is not known whether formoterol or budesonide passes into human breast milk. In rats, small amounts of formoterol have been detected in maternal milk. Administration of Symbicort Turbuhaler to women who are breastfeeding should only be considered if the expected benefit to the mother is greater than any possible risk to the child.

Effects on ability to drive and use machines
Symbicort Turbuhaler does not affect the ability to drive or use machines.

Undesirable effects
Since Symbicort Turbuhaler contains both budesonide and formoterol, the same pattern of undesirable effects as reported for these substances may occur. No increased incidence of adverse reactions has been seen following concurrent administration of the two compounds. The most common drug related adverse reactions are pharmacologically predictable side-effects of beta$_2$-agonist therapy, such as tremor and palpitations. These tend to be mild and usually disappear within a few days of treatment.

Adverse reactions, which have been associated with budesonide or formoterol, are given below.

Common (>1/100)	*Central nervous system:*	Headache
	Cardiovascular system:	Palpitations
	Musculoskeletal system:	Tremor
	Respiratory tract:	Candida infections in the oropharynx, mild irritation in the throat, coughing, hoarseness
Uncommon	*Cardiovascular system:*	Tachycardia
	Musculoskeletal system:	Muscle cramps
	Central nervous system:	Agitation, restlessness, nervousness, nausea, dizziness, sleep disturbances
Rare (<1/1000)	*Skin:*	Exanthema, urticaria, pruritus
	Respiratory tract:	Bronchospasm

Very rare undesirable effects, some of which are of a potentially serious nature include:

Budesonide: Psychiatric symptoms such as depression, behavioural disturbances (mainly in children), signs or symptoms of systemic glucocorticosteroid effects (including hypofunction of the adrenal gland), immediate or delayed hypersensitivity reactions (including dermatitis, angioedema and bronchospasm), bruising.